REMARKS / ARGUMENTS

Reconsideration of the application as amended is respectfully requested.

Pursuant to the previous requirement for restriction, the applicant inadvertently, through typographical error, elected the subject matter that was identified as Group I. Applicant wishes to amend and clarify this previous election and elect for current and further examination the invention construed by the Examiner to be set forth in Group II, claims 1-4 of the application.

Concerning this previously requested restriction of the claims and election of a species, Applicant suggests that the examiner has failed to make a prima facie case requiring such restriction, or that the species are "unconnected in design, operation, or effect". M.P.E.P. 808.01 The examiner has failed to provide an explanation as to whether the species claimed herein are in separate classifications, hold separate status in the art, or represent a different field of search. M.P.E.P. 808.02.

Applicant suggests that each embodiment shown, described, and claimed represent solutions to common motivation, and therefore all incorporate species that have a close relationship to one another in design, operation, and effect. M.P.E.P. 802.01. Consequently, the election is requested to be considered as with traverse.

Claims 1-4 were rejected under 35 U.S.C. 112, first paragraph Claim 1 has been amended above to eliminate the term "in particular". It is felt that this amendment overcomes the rejection cited in Paragraph 13 of the Examiner's Action.

In addition, claims 1-4 were also rejected under 35 U.S.C. 112, first paragraph, in that Claim 1 is directed to a method for treating diseases associated with

qualitative/quantitative changes in blood extracellular DNA, including treatment of a genus of fungal infections. Applicant wishes to clarify the underlying inventions is directed to Hypersensitivity (also called hypersensitivity reaction), which refers to undesirable (damaging, discomfort-producing and sometimes fatal) reactions produced by the normal immune system. Hypersensitivity reactions require a pre-sensitized (immune) state of the host. The four-group classification was expounded by P. H. G. Gell and Robin Coombs in 1963 as indicated in the Table Below:

Table 1: **Coombs and Gell classification**

Type	Alternative names	Often mentioned disorders	Mediators
I	Allergy (immediate)	Atopy Anaphylaxis Asthma	IgE
II	Cytotoxic, antibody-dependent	Autoimmune hemolytic anemia Thrombocytopenia Erythroblastosis fetalis Goodpasture's syndrome	IgM or IgG (Complement)
III	Immune complex disease	Serum sickness Arthus reaction Systemic lupus erythematosus (SLE)	IgG (Complement)
IV	Delayed-type hypersensitivity (DTH), cell-mediated immune memory response, antibody-independent	Contact dermatitis Mantoux test Chronic transplant rejection Multiple sclerosis	T-cells
V	Autoimmune disease	Grave's disease Myasthenia Gravis	T-cells

	Hashimoto's thyroiditis Systemic lupus erythematosus

LUPUS do not belongs to delayed-type hypersensitivity reaction and consequently is outside the scope of present invention.

According to the disclosure "it was established that blood extracellular DNA including extracellular DNA of bacteria, fungi and protozoa promotes development of diseases". In LUPUS, extracellular DNA is recognized not as the part of etiological mechanism, but as resulting component of disease, when apoptic DNA from dying cells induce synthesis of anti-DNA antibodies and resulting DNA-antiDNA antibody complexes raise the Type III hypersensitivity pathology. The ultimate goal of application of DNASE in LUPUS is inhibition of DNA-antibody complexes formation.

Additionally, Claims 1-4 were rejectedunder 35 U.S.c. 112, first paragraph, as failing to describe in the specification adequate subject matter to enable one skilled in the art to practice the proposed innovation. Applicant wishes to clarify that to a person having ordinary skill in the art of identifying and treating fungal infections, *Candidiasis* is one of the most common human fungi infection. *Candidiasis* is the "gold standard" model to search for a cure for human fungi disease. *C.Albicans* is typical representative of fungi model disease.

It is commonly accepted to those having ordinary skill in the relevant art that if a candidate drug works for candidiasis, it would work also for other minor fungi disease. In support of this, applicant wishes to direct attention to US Patent 5,833,946 dealing

with the dissemination of fungal infections in which an animal model and method of prophylaxis is described which claiming a method for identifying medicaments useful for preventing systemic Candidiasis.) *See also* Katsuhiko Kamei, Makoto Miyaji, Animal Models in Mycology, Schmidt A, Weber OF (eds): Animal Testing in Infectiology. Contrib Microbiol. Basel, Karger, 2001, vol 9, pp 45-57.

Thus, particular animal Candidiasis model is very highly predictive for efficacy in variety of human fungi diseases. Skilled person, knowing the method to treat Candidiasis, will not require any experimentation for extension of said method for other fungi desease. (While expert concern on predictivity of animal models is definitely valid for such desease as cancer, this is not true with infections)

This is further confirmed by the fact that once developed for one indication, the anti-fungal medicines prescribed for treatment of other fungal infections without change of dose. That is simply illustrated in patient leaflet of, for example, Abelcet (Amphotericin Lipid Complex): Your doctor has prescribed Abelcet for you, to treat a fungal infection such as systematic candidiasis, aspergillosis, cryptococcal meningitis, disseminated cryptococcosis, fusariosis, zygomycosis, blastomycosis or coccidiomycosis.

Hovewer, the dosing remains the same:

> "For severe systemic infections treatment is generally recommended at 5.0 mg/kg for at least 14 days. Abelcet should be administered by intravenous infusion at a rate of 2.5 mg/kg/hr. When commencing treatment with Abelcet for the first time it is recommended to administer a test dose immediately prior to the first infusion. The first infusion should be prepared according to the instructions then, over a period of approximately 15 minutes, 1mg of the infusion should be administered to the patient. After this amount has been administered the infusion

should be stopped and the patient observed carefully for 30 minutes. If the patient shows no signs of hypersensitivity the infusion may be continued. As for use with all amphotericin B products, facilities for cardiopulmonary resuscitation should be readily at hand when administering Abelcet for the first time, due to the possible occurrence of anaphylactoid reactions. Abelcet has been administered for as long as 28 months, and cumulative doses have been as high as 73.6g without significant toxicity."

In addition, Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by the Macanovic et al. disclosure. In undertaking to determine whether one reference anticipates another under 35 U.S.C. 102(a), a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 10583 (Fed. Circ.) Cert. Denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "read on" something disclosed in the reference, i.e. all limitations of the claim are found in the reference, or 'fully met' by it."

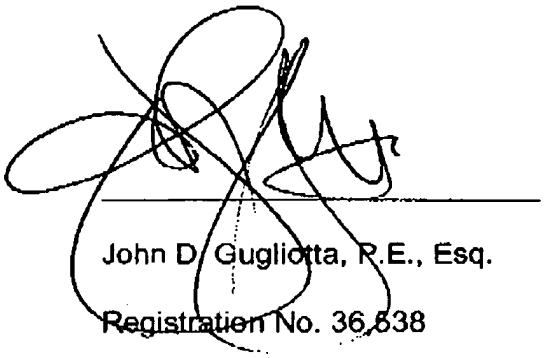
The present invention includes a number of features that are unanticipated in the above mentioned references, including treatment for diseases caused by mutations in somatic cells' genes by introduction of blood extracellular DNA destroying agent into a systemic blood circulation.

Accordingly, the rejection by the examiner under 35 U.S.C. 102(b) is

inappropriate.

Therefore, in view of foregoing amendments and clarifications, the applicant submits that allowance of the present application and all remaining claims, as amended, is in order and a formal Notice of Allowance is respectfully requested at the earliest possible date.

Respectfully submitted,



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